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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,826	08/14/2000	Eike Duweing	50615	8623
26474	7590	04/21/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/636,826

Applicant(s)

DUWEING ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55,59-93 and 95-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55,59,60 and 62-73 is/are allowed.
- 6) ☒ Claim(s) 61,74-93 and 95-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1638

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed August 6, 2003 has been entered.

Claims 1-54, 56-58 and 94 are cancelled.

Claims 55, 62, 64-66, 68-69, 71-81, 83-85, 87-89, 93 and 95-97 are currently amended

Claim 100 is newly added

Claims 55, 59-93 and 95-100 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Drawings

The drawings are objected to because the drawings contain a Figure 9C, but no Figure 9A or 9B. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 95-99 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth below.

Claims 95-99 are drawn to plant cells, protoplasts and plants transformed with a DNA construct as claimed in claim 55 which are resistant to stress or salt stress as a result of the expression of the DNA construct. Claim 55 is drawn to a DNA construct comprising the promoter of the *B. vulgaris* V-ATPase subunit c in isoform 2 as set forth in SEQ ID NO:1 operatively linked with a heterologous gene.

The specification describes plants cells transformed with a DNA construct comprising the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 operatively linked with a heterologous gene that is a luciferase reporter gene (pages 39-45). The specification does not describe any plant cell, protoplast or plants transformed with a DNA construct as claimed in claim 55 which plant cell, protoplast or plant is resistant to stress or salt stress as a result of the expression of the DNA construct. The specification also does not describe which heterologous genes, when expressed under the control of the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 in a plant cell, protoplast or plant, would confer to a plant cell, protoplast or plant tolerance to stress or to salt stress. Accordingly Applicant has not described a representative number of species falling within the scope of the claimed genus of plant cells, protoplasts and plants transformed with a DNA construct as claimed in claim 55 which plant cells, protoplasts or plants are resistant to any unspecified stress, or to salt stress, nor the

Art Unit: 1638

structural features unique to the genus. In particular, Applicant has not described a representative number of heterologous genes that could be expressed at a level sufficient to confer tolerance to any unspecified stress, or to salt stress, when expressed in a plant cell, plant or protoplast under the control of the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1, nor the structural features unique to these heterologous genes.

Claim 100 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth below.

Claim 100 is drawn to a DNA construct comprising a functional equivalent of the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 operatively linked to a heterologous gene.

The specification describes a DNA construct comprising the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1 operatively linked with a heterologous gene that is a luciferase reporter gene (pages 39-45). The specification does not describe other promoter sequences that are functionally equivalent to the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1. The specification also does not describe the structural and functional features of SEQ ID NO:1 that would be possessed by a functionally equivalent promoter, nor are these features set forth in the rejected claim. Accordingly Applicant has not described a representative number of promoter species falling within the scope of the claimed genus of all promoter sequences of unspecified sequence that exhibit any or all of the functional

Art Unit: 1638

characteristics of the *B. vulgaris* V-ATPase subunit c in isoform 2 promoter of SEQ ID NO:1, nor the structural features unique to the genus.

Claims 74-89 and 95-99 remain rejected, and newly added claim 100 is rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA constructs comprising the elected promoter of the *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO:1, expressing a heterologous gene, and producing a recombinant protein, does not reasonably provide enablement for DNA constructs comprising other promoters, or for plants, plant cells or protoplasts which are resistant to biotic or abiotic stress, or salt stress, for the reasons of record set forth in the office actions mailed April 23, 2002 and March 6, 2003.

The rejection under 35 U.S.C. 112, first paragraph, for scope of enablement, was not specifically addressed in the reply filed August 6, 2003. Accordingly, the rejection is maintained.

Claim 61 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the manner of recitation of specific heterologous genes, in the recitation of "a resistance-mediating gene", and in the recitation of "other medicinal, agronomical or other interest", for the reasons of record set forth in the office actions mailed October 22, 2002 and March 6, 2003.

Applicant's arguments filed August 6, 2003 have been fully considered but they are not persuasive.

Applicants argue that the claim is definite in light of the disclosure of suitable resistance-mediating genes, and other genes of interest, at page 6 of the specification. Applicants also argue

Art Unit: 1638

that they are uncertain how selection marker and resistance mediating genes are to be categorized if not as genes of medicinal, agronomical or other interest. (reply page 4)

The Office maintains that the disclosure at page 6 of the specification, indicating a preference for particular types of resistance mediating genes (insecticide resistance, herbicide resistance, microbial resistance, etc.) as heterologous genes, does not limit "a resistance-mediating gene" in the rejected claim, as the claim does not specify what type of resistance is mediated. With respect to the categorizing of selection marker and resistance mediating genes as genes of medicinal, agronomical or other interest, selection marker genes and genes that mediate specific resistance, Applicants arguments here are contrary to their previous assertion at pages 15-16 of the reply filed August 13, 2002, which stated that "the selection marker and the resistance-mediating gene do not fall within one of these categories. This is why the claim recites "other medicinal, agronomical or other interest."" With respect to the instant assertion, selection marker genes and genes that mediate specific resistance, while of agronomical interest in the context of the claimed invention, would not ordinarily be considered of medicinal or other interest in the context of the claimed invention. Furthermore, the specification does not disclose such genes as being of medicinal or other interest. The Office also maintains that the number and nature of the alternatives present in "other medicinal, agronomical or other interest" is unclear.

Claims 90 and 91 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, for the reasons of record set forth in the office actions mailed October 22, 2002 and March 6, 2003.

Art Unit: 1638

Applicant's arguments filed August 6, 2003 have been fully considered but they are not persuasive.

Applicants argue that the commonly accepted definition of "gene expression", such as the one set forth in the Oxford Dictionary of Biotechnology, indicates that one skilled in the art would understand that both transcription and translation are to take place in the process of the claims at issue. (reply pages 4-5)

The Office maintains that the definition of gene expression set forth in the Oxford Dictionary of Biotechnology does not limit the step of expressing the DNA construct in the rejected claims. The rejection is maintained because the rejected claims do not require that the expression of the DNA construct result in the production of a recombinant protein in a plant cell, plant or protoplast.

Claims 92, 93 and 95 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, for the reasons of record set forth in the office actions mailed October 22, 2002 and March 6, 2003.

Applicant's arguments filed August 6, 2003 have been fully considered but they are not persuasive.

Applicants argue that the step of expression is inherent to the method, as transformation with the claimed construct of a plant subjected to stress would necessarily result in the expression of the accompanying gene. (reply page 5)

The rejection is maintained because the rejected claims do not require subjecting the transformed plant to stress, or that a heterologous gene operatively linked to the claimed

Art Unit: 1638

promoter be expressed. The rejection is also maintained because claims 93 and 95 do not even require transforming a plant with a gene, heterologous or otherwise, to be expressed. Claim 92 requires only the step of transforming a plant with a DNA construct. Claims 93 and 95 require only transforming a plant with a V-ATPase subunit c isoform 2 promoter of SEQ ID NO:1, to which no gene for expression is even operatively linked.

Claim Rejections - 35 USC § 102

Newly added claim 100 is rejected under 35 U.S.C. 102(b) as being anticipated by Struve et al. (The Journal of Biological Chemistry, Vol. 265, No. 14, May 15, 1990, pages 7927-7932), for the reasons of record set forth in the office actions mailed October 22, 2002 and March 6, 2003.

Applicant's arguments filed August 6, 2003 have been fully considered but they are not persuasive.

Applicants reiterate their position that Struve et al. does not disclose a functionally equivalent promoter as such is contemplated by the present invention. (reply pages 5-6).

The Office maintains that the promoter taught by Struve et al. can be considered a functional equivalent of a V-ATPase subunit c isoform 2 promoter of SEQ ID NO:1, because neither the specific structure nor the specific function of the claimed promoter is limited in newly added claim 100. The promoter disclosed by Struve et al. can be considered a functional equivalent of a V-ATPase subunit c isoform 2 promoter of SEQ ID NO:1 because it is a polynucleotide sequence that functions as a promoter.

Art Unit: 1638

Remarks

Claims 55, 59, 60 and 62-73 are allowable.

Claims 55, 59-93 and 95-99 are deemed free of the prior art due to the failure of the prior art to teach or suggest a V-ATPase subunit c isoform 2 promoter of SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

Cynthia Collins 4/19/04